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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Hassan Mostafavi

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Vista IP Law Group (Varian)
1885 Lundy Ave, Suite 108
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EXAMINER

LAURITZEN, AMANDA L

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/655,920	Applicant(s) MOSTAFAVI, HASSAN	
	Examiner Amanda Lauritzen	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 6-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 6-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to communications filed 20 July 2010.

Response to Arguments

Applicant's arguments for the combination of references Kaufman, Takeo and Kalend have been fully considered and are persuasive; however, upon further consideration new grounds of rejection are presented in view of Kalend and Schweikard et al. (US 2004/0092815).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 6-10, 14, 15, 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Kalend et al. (US 5,784,431).

Kalend et al. disclose a method for gating a medical procedure, such as a radiation therapy procedure, in which a sequence of images is acquired, e.g., a simulation image prior to treatment and a series of portal images during treatment, as in col. 1, lines 21-47. A comparison among images is made and the images are matched or aligned with one another by an automatic process making use of fiducials within the image, as in col. 2, lines 19-22 and lines 36-67. The aligned images are displayed as a composite image in which a portal image is superimposed or overlaid with the simulation image or a portal image is overlaid with a preceding portal image to

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track patient movement during the procedure for driving the positioning assembly or gating the radiation beam, as in col. 5, lines 21-25, col. 4, lines 1-4 and lines 49-52, col. 6, line 61 – col. 7, line 3, col. 9, lines 14-21. A composite image or an alignment (matching) of two images is therefore directly used to turn the radiation beam on or off, as in col. 9, lines 14-21. The method is performed on a series of successive image frames such that multiple matched (composite) images are formed, as in col. 9, lines 14-16.

The method is useful for automatically repositioning the patient during a procedure such that any movement of the patient realigns the radiation beam with the treatment tumor site, so the motion information derived from the composite image is necessarily effective for controlling the medical procedure in real time. The method is computer controlled and therefore understood to be executed with a processor and a computer readable medium having stored instructions for carrying out the method steps, including acquiring a series of images and determining composite (matched) images useful for controlling a radiation procedure.

2. Claims 1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 14, 15, 16, 17 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Schweikard et al. (US 2004/0092815).

Schweikard et al. disclose method for gating a medical procedure, such as a radiation therapy procedure, in which a sequence of images is acquired prior to treatment for comparison with a series of images acquired during treatment to detect patient movement such that the position of the radiation beaming apparatus can be continuously adjusted to follow a moving target, as in the abstract, [0021], [0023], [0024], [0028]. A comparison is made between the pre-therapy and therapy images, including an image subtraction, with the resulting image being a

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composite image, [0044]. The direction of the radiation beaming apparatus is controlled based on any detected movement of the target based on the comparison of the images. Gray level values are compared for each pixel, with accumulated differences assisting in image matching for detection of target movement and ultimately for a corresponding adjustment of the radiation beam, [0044], [0024], [0021].

3. Claims 24-26, 32, 33, 34, 35, 36, 38, 39, 40, 41, 42, 47, 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Schweikard et al. (US 2004/0092815).

Schweikard et al. disclose a method of performing a medical procedure and corresponding system including providing a plurality of templates, each of which includes image and treatment data and corresponds to a phase of a physiological cycle, as in the abstract, [0021], [0023]. Prior to treatment, CT images of the patient are acquired, with each corresponding to a particular point in the respiratory cycle, as in [0023]. At each point within the respiration cycle, the position of the target is ascertained and this is used to direct the position of the radiation beaming apparatus to continuously focus on the target region during treatment, as in [0028]. During treatment, subsequent anatomical images are acquired for registering or matching with the template images acquired prior to treatment, as in [0024]. From this matching, the location and shape of the target region and phase of the respiratory cycle can be determined. The information regarding the location and shape of the target region is used to direct the radiation beam, with the direction of the beaming apparatus being the treatment data as it is one or more parameters used to control operation of a radiation machine.

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A plurality of digitally reconstructed radiographs (DRRs) are computed from the images acquired prior to treatment and each is compared with each live (input) image to determine a match, as in [0023], [0024], [0044]. A moving object (i.e., the target treatment location) is marked for enhanced viewing within each image, as in [0040].

The automated process of comparing images and using the matched image to position the radiation beam entails use of computer readable media and programmed instructions

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-5, 11-13, 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalend et al. in view of Takeo (US 6,125,166).

Kalend et al. disclose all features of the invention as substantially claimed, as detailed above, including control of a radiation medical procedure based in part on a composite image comprised of a matching of two images, as in col. 9, lines 14-21, but do not specifically address that this composite image is a subtraction image. However, Takeo teaches a method of forming energy subtraction images and discloses using contrast values to determine threshold values (col. 1, lines 50-64 for the subtraction process; also col. 19, lines 11-28 in which a contrast value is used). It would have been obvious to one of ordinary skill in the art at the time of invention to control a radiation therapy procedure based on a composite image that is comprised of a

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subtraction of two images, as a subtraction image highlights the differences between images and changes between successive image frames are being detected in Kalend et al., as in col. 9, lines 8-21. It would have been obvious to one ordinarily skilled in the art to use a contrast value of the image for reference as taught by Takeo in the method of Kalend et al., as gating a radiation procedure based on successive images enables tracking of patient motion due to breathing, for example, such that radiation is maintained at the target site and discontinued upon detection of movement above a threshold.

5. Claims 27, 31, 37, 43, 46, 49, 50, 53, 54, 55, 57, 58, 59, 62, 63, 64, 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schweikard et al. (US 2004/0092815) in view of Kalend (US 5,784,431).

Schweikard et al. discloses all features of the invention as substantially claimed, as detailed in above section 3, including adjusting the delivery of a radiation beam by controlling operation parameters of a radiation beam by directing the beam based on movement of a target treatment location, but are not particular to turning the radiation beam on or off based on movement of the target; however, in the same field of endeavor, Kalend teaches gating a medical procedure, such as a radiation therapy procedure, by making a comparison among images to track movement during a procedure for driving the positioning assembly of the radiation beam or turning the beam on or off, as in col. 5, lines 21-25, col. 4, lines 1-4 and lines 49-52, col. 6, line 61 – col. 7, line 3, col. 9, lines 14-21. The matching of two images is directly used to turn the radiation beam on or off, as in col. 9, lines 14-21. It would have been obvious to one ordinarily skilled in the art at the time of invention to include gating and on/off control of the radiation

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beam in addition to control of beam positioning in order to ensure that tissue beyond the target location is not irradiated in the case of unexpected or excessive patient movement. Kalend additionally teaches forming a composite image by superimposing a pre-therapy image with a live image.

6. Claims 28, 29, 44, 45, 51 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schweikard et al. (US 2004/0092815) in view of Kalend (US 5,784,431), as applied to claim 43 above, further in view of Florent et al. (US 2005/0002546).

The combination of Schweikard and Kalend includes all features of the invention as substantially claimed, including formation of composite images, but is not specific to image averaging; however, Florent et al. teach averaging of successive images for enhancement of objects within moving images, as in [0022] and the abstract. It would have been obvious to one ordinarily skilled in the art at the time of invention to average images for this same purpose. It additionally would have been obvious to use the averaged image in the comparison of images (subtraction), such that an image with reduced noise is used to determine the position of the target.

Claim Objections

7. Claim 53 is objected to as it depends from claim 52 which was previously cancelled. Correction is required. For examination purposes, claim 53 is construed to depend from claim 49.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amanda Lauritzen/
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit
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